CLAIM AMENDMENTS

IN THE CLAIMS:

This listing of the claims will replace all prior versions, and listing, of claims in the application or previous responses to office action:

1. **(Cancelled)** Please cancel Claim 1 without prejudice or disclaimer.

2. (Cancelled).

3. **(Cancelled)** Please cancel Claim 3 without prejudice or disclaimer.

4. **(Cancelled)** Please cancel Claim without prejudice or disclaimer.

5. **(Cancelled)** Please cancel Claim 5 without prejudice or disclaimer

6. **(Currently Amended)** A plasma colloid replacement fluid for replacing target receptor molecules contaminated with at least one toxin after the contaminated target receptor molecules have been removed from a patient's blood during very large pore hemofiltration which **creates an ultrafiltrate stream and** avoids removal of significant amounts of immunoglobulins comprising:

a pharmaceutical grade balanced salt solution having **albumin molecules or other** clean target receptor molecules corresponding with the contaminated target receptor molecules **in concentrations selected to adequately replenish ongoing losses** ~~**which have been removed**~~ from the patient's blood during the very large pore hemofiltration which avoids removal of significant amounts of immunoglobulins **in the ultrafiltrate stream**; and

the clean target receptor molecules **selected from the group** consisting ~~**essentially**~~ of albumin**[[,]]** **molecules and other clean** receptor molecules and carrier molecules with sufficient ~~**clean**~~ albumin **molecules** to maintain adequate plasma oncotic pressure during the very large pore hemofiltration which avoids removal of significant amounts of immunoglobulins **in the ultrafiltrate stream**.

7. (Cancelled).

8. (Original) The fluid of Claim 6 further comprising a concentration of albumin in the fluid greater than approximately 0.5 grams per one hundred milliliters.

9. (Original) The fluid of Claim 6 further comprising a concentration of albumin in the fluid less than approximately twenty grams per one hundred milliliters.

10. (Previously Presented) The fluid of Claim 6 further comprising the plurality of clean target receptor molecules corresponding with a plurality of target receptor molecules contaminated with more than one toxin removed from the patient's blood.

11. **(Currently Amended)** A plasma colloid replacement fluid kit for attachment to an extracorporeal blood circuit during very large pore hemofiltration which **creates an ultrafiltrate stream and** avoids removal of significant amounts of immunoglobulins, the kit comprising:

a plasma colloid replacement fluid and a reservoir **source** containing the plasma colloid replacement fluid;

the reservoir **source** having at least one port operable to communicate the plasma colloid replacement fluid from the reservoir **source**;

a coupling operable to allow flow of the plasma colloid replacement fluid from the port to the **patient's blood circulatory system** ~~extracorporeal blood circuit~~;

the plasma colloid replacement fluid formed in part by a pharmaceutical grade balanced salt solution, suitable for infusion into **the** **[[a]]** patient's blood circulatory system, with a concentration of clean albumin at least sufficient to maintain a prescribed albumin concentration in the patient's blood circulatory system;

the concentration of albumin in a range from 0.5 gm/100 ml to 10.0 gm/100 ml **and optionally other clean target receptor molecules**;

the ~~other~~ clean target receptor molecules disposed in the replacement fluid operable to bind target molecules thereto for removal during the very large pore hemofiltration which avoids removal of significant amounts of immunoglobulins **in the ultrafiltrate stream**; **[[and]]**

the clean target receptor molecules operable to attract target molecules from tissue spaces and tissue binding sites of the patient; and

the clean target receptor molecules selected from the group consisting of receptor molecules and carrier molecules.

12-16. (Cancelled)

17. **(Currently Amended)** An extracorporeal blood circuit for filtration of a patient's blood to remove target molecules and target complex molecules, comprising:

the blood circuit operable to remove and to return a portion of the patient's blood;

a blood filter operably coupled with the blood circuit to allow the portion of the patients' blood to flow therethrough;

the blood filter and the circuit operable to form a stream of filtered blood and a stream of an ultrafiltrate;

the blood filter and other portions of the blood circuit operable to remove the ultrafiltrate from the portion of the patient's blood with ultrafiltration rates between approximately two liters per hour and twenty liters per hour;

the blood filter having **a nominal** ~~**an effective**~~ molecular weight cutoff greater than 150,000 Daltons to sieve more than a nominal amount of the target molecules and the target complex molecules from the portion of the patient's blood;

the ~~**effective**~~ molecular weight cutoff of the blood filter selected to avoid removal of significant amounts of immunoglobulins from the portion of the patients' blood;

a source for infusing a replacement fluid, having clean target receptor molecules, into the blood circuit to provide sufficient clean target receptor molecules to attract inflammatory mediators and toxins from tissue spaces and tissue binding sites in the patient;

the clean target receptor molecules in the replacement fluid replacing the target **receptor** molecules ~~**and target complex molecules**~~ sieved from the portion of the patient's blood by the blood filter; and

the replacement fluid **comprising** ~~**consisting essentially of**~~ a pharmaceutical grade balanced salt solution with sufficient clean albumin to maintain adequate plasma oncotic pressure with ultrafiltration rates between approximately two liters per hour and twenty liters per hour ~~**and other target receptor molecules**~~ in a sufficient concentration to adequately replenish ongoing losses.

18. **(New)** The extracorporeal blood circuit of Claim 17 wherein the replacement fluid comprises a concentration of albumin in the fluid greater than approximately 0.5 grams per one hundred milliliters.

19. **(New)** The extracorporeal blood circuit of Claim 17 wherein the replacement fluid comprises a concentration of albumin in the fluid less than approximately twenty grams per one hundred milliliters.

20. **(New)** The extracorporeal blood circuit of Claim 17 wherein the blood filter comprises a nominal molecular weight cut off less than 5,000,000 Daltons.

21. **(New)** The extracorporeal blood circuit of Claim 17 wherein the blood filter comprises a nominal molecular weight cut off less than 1,000,000 Daltons.

22. **(New)** The extracorporeal blood circuit of Claim 17 wherein the blood filter comprises a nominal molecular weight cut off less than 500,000 Daltons.

REMARKS

This Application has been carefully reviewed in light of the Office Action mailed April 17, 2007. At the time of the Office Action, Claims 1, 3-6, 8-11 and 17 were pending in this Application. Claim 17 was allowed and Claims 1, 3-6, and 8-11 were rejected. Claims 5, 6, 11 and 17 have been amended to further define various features of Applicants' invention.

Claims 2, 7 and 12-16 were previously cancelled without prejudice or disclaimer. Claims 1, 3, 4 and 5 have been cancelled by this response without prejudice or disclaimer. New Claims 18-22 have been added. Applicants respectfully request reconsideration and favorable action in this case.

Office Interview

Applicants agree with the Examiner's Interview Summary mailed on May 11, 2007 concerning the office interview conducted on May 9, 2007.

Applicants appreciated the Examiner's comments concerning various proposed amendments to the pending claims. Applicants also appreciated the Examiner's careful review of the Specification as part of the interview and comparison of the Specification with the proposed amendments.

Terminal Disclaimer

A terminal disclaimer with respect to copending patent application Serial No. 11/387,556 filed on March 23, 2006 entitled "Method and System for Colloid Exchange Therapy" is enclosed. The Commissioner is authorized to charge $130 to the Deposit Account No. 50-2148 of Baker Botts L.L.P.

Rejections under 35 U.S.C. § 102

Claims 1, 3-6 and 8-10 were rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,900,720 issued to Ronald Kotitschke ("Kotitschke"). Applicants respectfully traverse and submit the cited art does not teach all of the elements of the claimed embodiments of the invention.

Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1997). Furthermore, "the identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co. Ltd.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Applicants respectfully submit that the cited art as anticipatory by the Examiner cannot anticipate the rejected Claims, because the cited art does not show all of the elements of the present Claims.

Claim 6 has been further amended to call for various features which are neither shown nor taught by Kotitschke or other references cited by the Examiner. For example, amended Claim 6 calls for a plasma colloid replacement fluid with ". . . albumin molecules and other clean target receptor molecules . . . in concentrations selected to adequately replenish ongoing losses . . . ." Amended Claim 6 also calls for ". . . the clean target receptor molecules selected from the group consisting of albumin molecules and other clean receptor molecules and carrier molecules with sufficient albumin molecules to maintain adequate plasma oncotic pressure during the very large pore hemofiltration which avoids removal of significant amounts of immunoglobulins in the ultrafiltrate stream." As noted during the interview with the Examiner, Kotitschke does not show or teach a replacement fluid having various features as defined in amended Claim 6. Kotitschke expressly teaches a replacement fluid for use in plasmapheresis which is substantially different from Applicants' invention related to very large pore hemofiltration. For example, Kotitschke's replacement fluid expressly contains immunoglobulins.

During the interview the Examiner also made reference to various blood replacement fluids and blood substitutes such as shown in U.S. Patent No. 5,661,124 issued to Steven J. Hoffman et al. (hereinafter "Hoffman"). As noted during the interview with the Examiner blood substitutes such as shown in Hoffman may be used when it is not practical to infuse a patient with donated blood. Blood substitutes may be appropriate for use when substantial amounts of blood have been lost from a patient during an accident resulting in serious injury or during a major surgery. As noted during the interview with the Examiner, one of the features of Applicants' invention includes providing a replacement fluid with clean target receptor molecules which replenish contaminated target receptor molecules which have been removed from a patient's blood during very large pore hemofiltration. As noted during the interview and as discussed in more detail in the Specification, the use of a replacement fluid having clean target receptor molecules as further defined in amended Claim 6 substantially

enhances *in situ* removal of toxins including, but not limited to, removal of toxins from a patient's body tissues by interaction with albumin and optionally other clean target receptor molecules. Neither Hoffman nor any of the other references cited by the Examiner with respect to blood substitutes show or teach various features of Applicants' invention as defined in amended Claim 6.

Claims 8, 9 and 10 as amended are dependent from amended Claim 6. Since Claim 6 as amended is now deemed allowable, Claims 5, 8, 9 and 10 as amended are allowable.

Applicants request withdrawal of all rejections and allowance of Claims 6, 8, 9 and 10 as amended.

Rejections under 35 U.S.C. § 103

Claim 11 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Kotitschke, in view of U.S. Patent No. 4,968,432 issued to Glenn D. Antwiler ("Antwiler"). Applicants respectfully traverse and submit the cited art combinations, even if proper, which Applicants do not concede, does not render the claimed embodiments of the invention obvious.

In order to establish a prima facie case of obviousness, the references cited by the Examiner must disclose all claimed limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Even if each limitation is disclosed in a combination of references, however, a claim composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. KSR Int'l. Co. v. Teleflex Inc., 550 U.S. ____, 2007 WL 1237837 (2007). Rather, the Examiner must identify an apparent reason to combine the known elements in the fashion claimed. Id. "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Id., citing In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006). Finally, the reason must be free of the distortion caused by hindsight bias and may not rely on ex post reasoning. KSR Int'l. In addition, evidence that such a combination was uniquely challenging or difficult tends to show that a claim was not obvious. Leapfrog Enterprises, Inc. v. Fisher-Price, Inc. and Mattel, Inc., Case No. 06-1402, p. 10 (Fed.Cir. 2007), citing KSR Int'l., 2007 WL 1237837, at *15.

Claim 11 has been further amended to call for various features which are neither shown nor taught by Kotitschke or other reference cited by the Examiner. Claim 11 as amended to call for various features of Applicants' invention similar to the amendments made to Claim 6. Applicants request withdrawal of all rejections and allowance of Claim 11 as amended.

Allowed Claim

Claim 17 was previously allowed by the Examiner. The Examiner indicated during the interview that Claim 17 as further amended to better define the scope of Applicants' invention would also likely be allowable. Applicants request allowance of Claim 17 as further amended.

New Claims

New Claims 18-22 are dependent from amended Claim 17. Since amended Claim 17 is now deemed allowable, new Claims 18-22 are allowable.

CONCLUSION

Applicants have now made an earnest effort to place this case in condition for allowance in light of the amendments and remarks set forth above. Applicants respectfully request reconsideration of the pending Claims as amended.

Applicants believe there are no fees due at this time, however, the Commissioner is hereby authorized to charge any fees necessary or credit any overpayment to Deposit Account No. 50-2148 of Baker Botts L.L.P.